

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

2:16 MD 1203

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated July 20, 2004, Dr. Johnson attested in Part II of claimant's Green Form that Ms. Schuchmann suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction

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3. (...continued)  
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

in the range of 50% to 60%.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix B-1,<sup>5</sup> Level II benefits in the amount of \$107,795.<sup>6</sup>

In the report of claimant's echocardiogram, Dr. Johnson stated that Ms. Schuchmann had moderate mitral regurgitation. Dr. Johnson did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In September, 2005, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. Johnson's finding that claimant

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4. Dr. Johnson also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

5. The Trust determined, and claimant did not dispute, that the duration of Ms. Schuchmann's Diet Drug use was 60 days or less. Accordingly, Ms. Schuchmann's claim only is payable, if at all, on Matrix B-1. See Settlement Agreement § IV.B.2.d.(2)(b).

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

had moderate mitral regurgitation because there only is mild mitral regurgitation. Dr. Oliner explained that the "color gain is too high, with excessive pixelation and color outside the heart."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Schuchmann's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant argued that the attesting physician's conclusions should be accepted unless they are "extreme or excessive." In further support of her claim, Ms. Schuchmann submitted an echocardiogram report prepared by Alan R. Maniet, D.O., F.A.A.I.M. Dr. Maniet stated he reviewed claimant's echocardiogram and concluded that it represented moderate mitral regurgitation with an RJA/LAA ratio of 24%. Dr. Maniet also noted that the "gain settings, color Doppler settings and other technical information that is recorded within the study are accurate and conform to established criteria." Dr. Maniet submitted three still frames purporting to demonstrate claimant's moderate mitral regurgitation. Claimant also contended that "[q]uantifying the level of regurgitation

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Schuchmann's claim.

shown on an echocardiogram is inherently subjective."<sup>8</sup> Finally, claimant suggested that the auditing cardiologist and the Trust did not properly apply the reasonable medical basis standard established in the Settlement Agreement and that the auditing cardiologist simply substituted his own opinion for that of the attesting physician.<sup>9</sup>

The Trust then issued a final post-audit determination again denying Ms. Schuchmann's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On May 30, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6341 (May 30, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

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8. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed Ms. Schuchmann's echocardiogram.

9. Claimant also asserted that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant also referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how those filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 7, 2006, and claimant submitted a sur-reply on December 12, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>10</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Schuchmann reasserts many of the arguments she made in contest. In addition, claimant suggests that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation. According to claimant, "[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'"<sup>11</sup>

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard and argues that Dr. Oliner properly applied the reasonable medical basis standard in evaluating Ms. Schuchmann's claim. The Trust also contends that Dr. Maniet's review does not establish a reasonable medical basis for Dr. Johnson's representation that claimant has moderate mitral regurgitation because he "measured in early systole" and "overtraced to include portions of the left ventricle and areas outside the jet."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no

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11. Ms. Schuchmann also argues that Dr. Oliner is biased against claimants and that his opinion should be viewed with skepticism. As the only "evidence" she offers in support of this assertion is an allegation that Dr. Oliner has wrongly denied other Matrix claims, this issue is irrelevant for resolution of this claim.

reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because the claimant's echocardiogram demonstrated only mild mitral regurgitation.

Dr. Vigilante explained:

I reviewed the Claimant's echocardiogram of July 20, 2004.... The usual echocardiographic views were obtained. This was an adequate quality echocardiographic study except during the color flow Doppler portion of the exam. There was clear evidence of excessive color gain with appropriate demonstration of low velocity flow and color artifact seen outside the blood pool. However, the Nyquist limit was appropriately set in the parasternal long axis view at 67 cm per second at a depth of 16 cm and in the apical views at 62 cm per second at a depth of 19 cm. The mitral leaflets appeared normal with normal excursion. There was no evidence of mitral valve prolapse nor mitral annular calcification. There was evidence of mitral regurgitation seen on color Doppler evaluation in the parasternal long axis view. In the apical four and two chamber views, a central jet of mitral regurgitation that did not go past the mid portion of the left atrium was noted. Visually, only mild mitral regurgitation was present. I digitized those cardiac cycles in the apical four chamber and two chamber views in which the mitral regurgitation was best evaluated. I then digitally traced and calculated the RJA and LAA. I determined that the LAA was 19.0 cm<sup>2</sup>. The largest representative RJA in the apical four chamber view measured 3.4 cm<sup>2</sup>. I was able to accurately determine this RJA in spite of the increased color gain noted on the study. I was able to exclude low velocity, non-mitral regurgitant artifact in the determination of the RJA. The largest representative RJA in the apical two chamber view was less than 2.0 cm<sup>2</sup>. Therefore, I calculated the largest representative RJA/LAA ratio to be 18%. Most of the RJA/LAA ratios were less than 15% in the apical four chamber view and less than 10% in the apical two



chamber view. I reviewed the screen shots of Dr. Maniet. His RJA measurement of 4.16 cm<sup>2</sup> was not representative of mitral regurgitation. A significant portion of this traced image included low velocity, non-mitral regurgitant flow. At most, the RJA was 3.4 cm<sup>2</sup>. I also evaluated Dr. Maniet's LAA measurement of 17.67 cm<sup>2</sup>. This was a somewhat off axis view of the left atrium. The correct measurement of the LAA was 19.0 cm<sup>2</sup>. My finding of mild mitral regurgitation corresponds with the findings of mild mitral regurgitation also found on two previous echocardiographic reports.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. We disagree with claimant's interpretation of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis standard" as more stringent than claimant contends, and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8)

overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26.

Although Dr. Maniet opined that the gain and color Doppler settings on claimant's echocardiogram were "accurate and conform to established criteria," Dr. Oliner and Dr. Vigilante determined that the study was not properly performed. In particular, Dr. Oliner observed that the "color gain is too high, with excessive pixelation and color outside the heart."<sup>12</sup> Dr. Vigilante also concluded that "[t]here was clear evidence of excessive color gain with appropriate demonstration of low velocity flow and color artifact seen outside the blood pool."

In addition, while Dr. Maniet opined that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 24%, Dr. Oliner and Dr. Vigilante reviewed claimant's echocardiogram and determined that it demonstrated only mild mitral regurgitation. In particular, Dr. Vigilante "calculated the largest representative RJA/LAA ratio to be 18%," but noted that "[m]ost of the RJA/LAA ratios were less than 15% in the apical four chamber view and less than 10% in the apical two chamber view."<sup>13</sup>

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12. For this reason as well, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Oliner merely substituted his opinion for that of the attesting physician. Instead, Dr. Oliner specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation, and claimant did not adequately refute this determination.

13. Claimant's Show Cause Record also includes the reports of  
(continued...)

Dr. Vigilante also reviewed the still frames Dr. Maniet submitted in support of his determination. Dr. Vigilante concluded that his RJA measurement "was not representative of mitral regurgitation" and that "[a] significant portion of this traced image included low velocity, non-mitral regurgitant flow." With respect to Dr. Maniet's LAA measurement, Dr. Vigilante observed, "This was a somewhat off axis view of the left atrium."<sup>14</sup> Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Schuchmann's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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13. (...continued)  
two echocardiograms performed on November 2, 2001 and August 30, 2002, each of which noted only mild mitral regurgitation.

14. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.